510(k) Summary

Introduction

This summary is intended to comply with requirements of the SMDA and 21CFR§807.92. FDA may make this summary available to the public within 30 days following a finding of substantial equivalence.

510(k) Holder

CLARIANCE
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510(k) Correspondent

William (Bill) Jackson
W. F. Jackson Associates, LTD.
3101 Neal Ct., Cumming, GA.30041-6111
Tel: 678-341-9581

Date Prepared

July 5, 2012

Trade Name of Device

CLARIANCE Erisma-LP

Common Name of Device

Noncervical Pedicle Spine System

Classification Name

Noncervical, Pedicle System

510(k) Classification

Class II under regulation 21 CFR 888.3070 for Product Code MNH and MNI along with Class III for Product Code NKB

Predicate Devices

K052131 Expedium Spine System manufactured by Johnson & Johnson

K030840 Horizon Spinal System manufactured by Medtronic Sofamor Danek, Inc.

K001272 Xia Spine System manufactured by Howmedica Osteonics Corp.

Device Description

The Erisma™ LP instrumentation is designed for the surgical treatment of spinal pathologies. The treatment consists of the fusion of two or several vertebrae in order to restore spinal stability, with or without any other endocanalar concomitant surgical procedure.

Intended Use

When used as a pedicle screw fixation system of the non-cervical posterior spine in skeletally mature patients using allograft and/or autograft, the Erisma™ Spinal System is indicated as an adjunct to fusion for one or more of the following:

- Degenerative disc disease(Discogenic pain with degeneration of the disc confirmed by history and radiographic studies)
- Degenerative spondylolisthesis with objective evidence of neurologic impairment,
- Severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar-first sacral (L5-S1) vertebral joint
- Fracture,
- Dislocation,
- Scoliosis,
- Kyphosis,
- Spinal tumor,
- Failed previous fusion (pseudarthrosis).

Clinical Evaluation

CLARIANCE did not conduct, nor rely upon, clinical tests to determine substantial equivalence.

Non-Clinical Testing

Non-clinical testing was performed in order to validate the design against the company's specified design requirements, and to assure conformance with the following voluntary standards:

ASTM F1717 – 01 ASTM F1717-09 , Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model.

ASTM F1798 - ASTM F1798-97(Reapproved 2008), Standard Guide for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spinal Arthrodesis Implants.

Risk Management

This device has been designed to either completely eliminate or mitigate known health hazards associated with the use of the device. Health hazard risk reduction has been accomplished by rigorous application of a risk management program according to standard ISO 14971.

Substantial Equivalence

CLARIANCE believes that the Erisma-LP is safe and effective when used as instructed by knowledgeable and trained personnel, and is substantially equivalent to the legally marketed predicate device(s).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

AUG 13 2012

Clariance
% Mr. William Jackson
3101 Neal Court
Cumming, Georgia 30041

Re: K120469
Trade/Device Name: Erisma-LP
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: III
Product Code: NKB, MNH, MNI
Dated: July 05, 2012
Received: July 09, 2012

Dear Mr. Jackson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K120469

Device Name: Erisma-LP

Indications for Use:

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- Dislocation,
- Scoliosis,
- Kyphosis,
- Spinal tumor,
- Failed previous fusion (pseudarthrosis).

Prescription Use x (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K120469